



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Joel S. Greenberger

Title: PROTECTION FROM IONIZING
IRRADIATION OR
CHEMOTHERAPEUTIC DRUG
DAMAGE BY *IN VIVO* GENE
THERAPY

Appl. No.: 08/907,041

Filing Date: 08/06/1997

Examiner: S. Chen

Art Unit: 1632

DECLARATION UNDER 37 CFR § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Anatoly Dritschilo, declare that:

1. I am a Professor and Chair of the Department of Radiation Medicine and Chief of Radiation Oncology at Georgetown University Hospital. I am on the Board of Directors of the National Coalition for Cancer Research and on the Roster of Distinguished Scientific Advisors to the Radiological Society of North America. I am also a member of the Radiation Research Society.

2. I received my medical degree from The College of Medicine of New Jersey and trained at Cincinnati General Hospital and Harvard Medical School in radiation oncology.

3. I have over 20 years in practice, specializing in the treatment of breast and prostate cancer. I have published over 150 articles in the area of cancer research, including articles on liposomal delivery systems for antineoplastic and radiosensitizing agents, for which I

also hold a series of patents. Accordingly, I have a longstanding professional interest and research focus on drug delivery.

4. I have reviewed paragraphs 4 through 9 of the Office Action dated May 13, 2003, paragraphs 5 through 10 of the Office Action dated December 15, 2003, and the following passages of the references cited therein: pages 6, 13, 19 and 27 of Hartman et al. (European Publication No. 0 284 105 A2), and pages 236 and 238 of Ishiye et al. (FEMS Microbiology Letters, Vol. 97, pp. 235-241).

5. The Office Action dated December 15, 2003, states at paragraph 6 that TE buffer or Tris buffer “can be considered a pharmaceutically acceptable vehicle.”

6. As a medical doctor conversant in drug delivery technologies, I believe that TE buffer and Tris buffer are not considered in my field as a “pharmaceutically acceptable vehicle,” because they are neither inert nor otherwise medically acceptable. Thus, TE buffer is “harmful if swallowed” and “[i]rritating to eyes, skin and by inhalation.” See attached EG-Safety Data Sheet (APPENDIX 1). Similarly, Tris buffer is “harmful if swallowed or inhaled” and “causes irritation to skin, eyes and respiratory tract.” See attached J.T. Baker MSDS (APPENDIX 2).

7. The Office Action dated May 13, 2003, further states at paragraph 6 that Hartman et al. “teaches construction of a plasmid pMSE-4” and that the “buffer solution for the plasmid is considered a pharmaceutically acceptable vehicle.” The Office Action does not identify which “buffer solution” the examiner considers a pharmaceutically acceptable vehicle. However, the Office Action dated December 15, 2003, states at paragraph 6 that “[i]t was very well known in the art to use TE buffer as DNA storage buffer”, and at paragraph 7 that “plasmid pMSE-4 is stored in a DNA buffer solution and said buffer solution is considered a pharmaceutically acceptable vehicle.”

8. For the reasons I have enumerated in paragraph 6, however, TE buffer is not considered a pharmaceutically acceptable vehicle. While Hartman et al. also discloses potassium phosphate (see pages 6, 13 and 19), potassium acetate (see pages 13, 19) and Tris HCl (see page 27), none of these buffers is likewise considered to be a pharmaceutically acceptable vehicle, again because they are neither inert nor otherwise medically acceptable. Potassium phosphate “may be harmful if swallowed or inhaled” and “may cause irritation to skin, eyes, and respiratory tract.” See attached J.T. Baker MSDS (APPENDIX 3). In addition, potassium

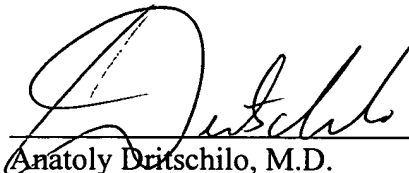
acetate "may be harmful if swallowed" and "may cause irritation to the skin and eyes." See attached ScholAR Chemistry MSDS (APPENDIX 4). Finally, Tris HCl is "harmful if swallowed" and "may cause irritation to skin, eyes, and respiratory tract." See attached J.T. Baker MSDS (APPENDIX 5).

9. The Office Action dated May 13, 2003, further states at paragraph 7 that Ishiye et al. "teaches construction of an expression vector containing coding sequence of E. coli HB101 gamma-glutamyltranspeptidase (GGT)" and that the "buffer solution containing the expression vector expressing GGT is considered a pharmaceutically acceptable vehicle." The Office Action does not identify which "buffer solution" is considered a pharmaceutically acceptable vehicle. The Office Action dated December 15, 2003, does state that "[i]t was very well known in the art to use TE buffer as DNA storage buffer" (paragraph 6), and that "plasmid pGGT298trp is stored in a DNA buffer solution and said buffer solution is considered a pharmaceutically acceptable vehicle" (paragraph 8).

10. For the reasons set out in paragraph 7, I do not believe that TE buffer is a pharmaceutically acceptable vehicle. While Ishiye et al. also discloses potassium phosphate (see page 236) and Tris HCl (see pages 236 and 238), none of these buffers is deemed a pharmaceutically acceptable vehicle, as explained in paragraph 8.

I hereby declare that all the statements made herein of my known knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements are so made punishable by fine or imprisonment, or both, under Section 101 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

5/10/04
Date


Anatoly Dritschilo, M.D.

EG-Safety Data Sheet (according to 91/155/EEC)

Revised on : 22.01.2003

Printing date: 22.01.2003

Reference: EG-MSDS/INT TE

Page 1 / 2

1. Identification of the substance/preparation and of the company

- Identification of the substance or preparation:

TE Buffer

- Company identification:

GENOMED Molekularbiologische und diagnostische Produkte GmbH (manufacturer)
Poststrasse 22, D-32584 Löhne/Germany
Tel: (49)-(0)5732/904-700; Fax: -7010

- Emergency Address:

GENOMED Molekularbiologische und diagnostische Produkte GmbH (manufacturer)
Poststrasse 22, D-32584 Löhne/Germany
Tel: (49)-(0)5732/904-700; Fax: -7010

2. Composition/information on ingredients

10 mM tris(hydroxymethyl)aminomethan hydrochloride (CAS # 77-86-1) in water, pH 8.0; contains 0.1 mM ethylenediaminetetraacetic acid (CAS # 6381-92-6).

3. Hazards identification

Harmful if swallowed. Irritating to eyes, skin and by inhalation.

4. First aid measures

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

5. Fire-fighting measures

Not inflammable. Choose extinguishing media according to environment conditions. Wear self contained breathing apparatus, approved gas mask and protective clothing to avoid contact with eyes and skin.

6. Accidental release measures

- personal precautions such as: Wear rubber or latex gloves, safety goggles and suitable protective clothing.
- methods for cleaning up such as: Wipe up liquid and dispose in accordance with state or local laws. Avoid aerosols. Clean and ventilate the concerning area after complete removal of the liquid.

7. Handling and storage

see point 8.

8. Exposure controls/personal protection

- respiratory protection: Use NIOSH/MSHA approved respirator if generating aerosols.
- hand protection: Rubber or latex gloves.
- eye protection: Safety goggles.
- skin protection: Suitable protective clothing.

9. Physical and chemical properties

- appearance: clear liquid
- pH: 8.0
- boiling point: N. I.
- melting point: N. I.
- specific gravity: N. I.
- vapor pressure: N. I.

10. Stability and reactivity

- conditions to avoid: strong oxidizers
- hazardous decomposition products: toxic fumes of carbon monoxide, carbon dioxide and nitrogen oxides.

Identification of the substance or preparation:

TE Buffer

11. Toxicological information

N. I.

12. Ecological information

On regular use no prejudice is to be expected.

13. Disposal considerations

The component should be disposed in accordance with state or local laws.

14. Transport information

None.

15. Regulatory information

European information:

Attention: This preparation has not yet been thoroughly tested.

R: 22

Harmful if swallowed.

R: 36/37/38

Irritating to eyes, skin and mucous membranes.

S: 26

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S: 36

Wear suitable protective clothing.

16. Other information

The above-mentioned data correspond to our present state of knowledge and experience. Although utmost care has been taken in the composition of this text, the publisher cannot be held responsible for any damage resulting from any eventual error in this publication.

MSDS Number: **T7111** * * * * * Effective Date: **09/10/02** * * * * * Supersedes:
11/02/01

MSDS**Material Safety Data Sheet**

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865



Mallinckrodt
CHEMICALS



24 Hour Emergency Telephone: 800-559-2151
CHEMTREC: 1-800-424-0300

National Response in Canada
CANUTEC: 613-996-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National
Response Center emergency numbers to be
used only in the event of chemical emergencies
involving a spill, leak, fire, exposure or accident
involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-562-2537) for assistance.

TRIS(HYDROXYMETHYL) AMINOMETHANE

1. Product Identification

Synonyms: TRIS; 2-Amino-2-(hydroxymethyl)-1,3-propanediol; THAM;
Tromethamine (USP); TRIS (Base); Trisamine

CAS No.: 77-86-1

Molecular Weight: 121.14

Chemical Formula: H₂NC(CH₂OH)₃

Product Codes:

J.T. Baker: 1500, 4099, 4102, 4107, 4109, X171, X172

Mallinckrodt: 1806, 7732

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Tris	77-86-1	99 - 100%	Yes

3. Hazards Identification

Emergency Overview

WARNING! HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 1 - Slight

Flammability Rating: 1 - Slight

Reactivity Rating: 1 - Slight

Contact Rating: 2 - Moderate

Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES

Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:

Causes irritation to the respiratory tract. Symptoms may include coughing, shortness of breath.

Ingestion:

Mild alkali. Causes irritation and reddening to the mucous membranes of the mouth, esophagus, and gastrointestinal tract. Symptoms may include nausea, vomiting and diarrhea. Large oral doses may cause weakness, collapse, blood clotting and coma. Estimated lethal dose: 50 grams.

Skin Contact:

Causes irritation to skin. Symptoms include redness, itching, and pain.

Eye Contact:

Causes irritation, redness, and pain.

Chronic Exposure:

Chronic dermatitis may follow skin contact.

Aggravation of Pre-existing Conditions:

No information found.

4. First Aid Measures

Inhalation:

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Skin Contact:

Immediately flush skin with plenty of soap and water for at least 15 minutes. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get medical attention.

5. Fire Fighting Measures

Fire:

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. Slight fire hazard when exposed to heat or flame.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Water spray, dry chemical, alcohol foam, or carbon dioxide.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Remove all sources of ignition. Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from any source of heat or ignition. Isolate from oxidizing materials. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

None established.

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator.

WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Transparent, colorless crystals.

Odor:

Slight characteristic odor.

Solubility:

550 mg/mL

Density:

No information found.

pH:

10.4 (0.1 molar solution)

% Volatiles by volume @ 21C (70F):

0

Boiling Point:

219 - 220C (426 - 428F)

Melting Point:

171 - 172C (340 - 342F)

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Copper, brass, aluminum, and oxidizing agents.

Conditions to Avoid:

Heat, incompatibles.

11. Toxicological Information

Tris: oral rat LD50: 5900 mg/kg.

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Tris (77-86-1)	No	No	None

12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----				
Ingredient	TSCA	EC	Japan	Australia
Tris (77-86-1)	Yes	Yes	Yes	Yes

-----\Chemical Inventory Status - Part 2\-----				
Ingredient	Korea	DSL	NDL	Phil.
Tris (77-86-1)	Yes	Yes	No	Yes

-----\Federal, State & International Regulations - Part 1\-----				
Ingredient	-SARA 302- RQ	TPQ	-SARA 313- List	Chemical Catg.
Tris (77-86-1)	No	No	No	No

-----\Federal, State & International Regulations - Part 2\-----			
Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
Tris (77-86-1)	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **1** Flammability: **1** Reactivity: **0**

Label Hazard Warning:

WARNING! HARMFUL IF SWALLOWED OR INHALED. CAUSES IRRITATION TO SKIN, EYES AND RESPIRATORY TRACT.

Label Precautions:

Avoid contact with eyes, skin and clothing.

Wash thoroughly after handling.

Use only with adequate ventilation.

Keep container closed.

Avoid breathing dust.

Label First Aid:

If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. In all cases, get medical attention.

Product Use:

Laboratory Reagent.

Revision Information:

MSDS Section(s) changed since last revision of document include: 3.

Disclaimer:

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Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)

MSDS Number: **P6038** * * * * * Effective Date: **05/14/03** * * * * *
Supersedes: **11/02/01**

MSDS**Material Safety Data Sheet**

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865



Mallinckrodt
CHEMICALS



24 Hour Emergency Telephone: 908-659-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-956-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

POTASSIUM PHOSPHATE MONOBASIC

1. Product Identification

Synonyms: Phosphoric acid, monopotassium salt; Potassium dihydrogen phosphate

CAS No.: 7778-77-0

Molecular Weight: 136.09

Chemical Formula: KH₂PO₄

Product Codes:

J.T. Baker: 1491, 3245, 3246, 3247, 3248, 3249, 4008, 4921

Mallinckrodt: 2929, 7096, 7100, 7746

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Potassium Phosphate Monobasic	7778-77-0	99 - 100%	Yes

3. Hazards Identification

Emergency Overview

CAUTION! MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. MAY BE HARMFUL IF SWALLOWED OR INHALED.

J.T. Baker SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 0 - None

Flammability Rating: 0 - None

Reactivity Rating: 0 - None

Contact Rating: 1 - Slight

Lab Protective Equip: GOGGLES; LAB COAT

Storage Color Code: Orange (General Storage)

Potential Health Effects

Inhalation:

May cause mild irritation to the respiratory tract.

Ingestion:

Phosphates are slowly and incompletely absorbed when ingested, and seldom result in systemic effects. Such effects, however, have occurred. Symptoms may include vomiting, lethargy, diarrhea, blood chemistry effects, cardiac effects and central nervous system effects. The toxicity of phosphates is because of their ability to sequester calcium. Acute potassium intoxication by mouth is rare because large single doses usually induce vomiting and because in the absence of pre-existing kidney damage, potassium is rapidly excreted. Potassium poisoning can result in heart effects, change in respiration rate, tingling in the extremities, heaviness in the limbs, nausea and diarrhea.

Skin Contact:

Irritant due to its acidic nature. May cause inflammation and pain on prolonged contact, especially with moist skin.

Eye Contact:

May cause irritation, redness and pain.

Chronic Exposure:

May sequester calcium and cause calcium phosphate deposits in the kidneys.

Aggravation of Pre-existing Conditions:

Persons with impaired kidney function may be more susceptible to the effects of the substance.

4. First Aid Measures

Inhalation:

Remove to fresh air. Get medical attention for any breathing difficulty.

Ingestion:

If swallowed, give several glasses of water to drink to dilute. If large amounts were swallowed or symptoms occur, get medical advice. Never give anything by mouth to an unconscious person.

Skin Contact:

Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention if irritation develops.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get medical attention if irritation persists.

5. Fire Fighting Measures

Fire:

Not considered to be a fire hazard.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Use any means suitable for extinguishing surrounding fire.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

None established.

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator.

WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Safety glasses. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

White granular powder.

Odor:

Odorless.

Solubility:

22 g in 100 g of water.

Density:

2.34

pH:

No information found.

% Volatiles by volume @ 21C (70F):

0

Boiling Point:

400C (752F) Loses water and becomes metaphosphate

Melting Point:

253C (487F)

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Phosphorus oxides may form when heated to decomposition.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

No incompatibility data found.

Conditions to Avoid:

No information found.

11. Toxicological Information

No LD50/LC50 information found relating to normal routes of occupational exposure.

-----\Cancer Lists\-----			
Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
-----	-----	-----	-----

Potassium Phosphate Monobasic
(7778-77-0)

No

No

None

12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----				
Ingredient	TSCA	EC	Japan	Australia
Potassium Phosphate Monobasic (7778-77-0)	Yes	Yes	Yes	Yes

-----\Chemical Inventory Status - Part 2\-----				
Ingredient	Korea	DSL	Phil.	Canada
Potassium Phosphate Monobasic (7778-77-0)	Yes	Yes	No	Yes

-----\Federal, State & International Regulations - Part 1\-----				
Ingredient	-SARA 302- RQ	TPQ	-SARA 313- List	Chemical Catg.
Potassium Phosphate Monobasic (7778-77-0)	No	No	No	No

-----\Federal, State & International Regulations - Part 2\-----			
Ingredient	CERCLA	-RCRA- 261.33	-TSCA- 8(d)
Potassium Phosphate Monobasic (7778-77-0)	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **1** Flammability: **0** Reactivity: **0**

Label Hazard Warning:

CAUTION! MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT. MAY BE HARMFUL IF SWALLOWED OR INHALED.

Label Precautions:

Avoid contact with eyes, skin and clothing.

Wash thoroughly after handling.

Avoid breathing dust.

Keep container closed.

Use with adequate ventilation.

Label First Aid:

If inhaled, remove to fresh air. Get medical attention for any breathing difficulty. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists. If swallowed, give several glasses of water to drink to dilute. If large amounts were swallowed or symptoms occur, get medical advice. Never give anything by mouth to an unconscious person.

Product Use:

Laboratory Reagent.

Revision Information:

MSDS Section(s) changed since last revision of document include: 8.

Disclaimer:

Mallinckrodt Baker, Inc. provides the information contained herein in good faith but makes no representation as to its comprehensiveness or accuracy. This document is intended only as a guide to the appropriate precautionary handling of the material by a properly trained person using this product. Individuals receiving the information must exercise their independent judgment in determining its appropriateness for a particular purpose. MALLINCKRODT BAKER, INC. MAKES NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE INFORMATION SET FORTH HEREIN OR THE PRODUCT TO WHICH THE INFORMATION REFERS. ACCORDINGLY, MALLINCKRODT BAKER, INC. WILL NOT BE RESPONSIBLE FOR DAMAGES RESULTING FROM USE OF OR RELIANCE UPON THIS INFORMATION.

Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)



MATERIAL SAFETY DATA SHEET

5100 W. Henrietta Rd.
West Henrietta, NY 14586
TEL: (866) 260-0501

MSDS No. 9420406
Effective Date: November 14, 2002

SECTION I NAME 24 HOUR EMERGENCY ASSISTANCE

Product	Potassium Acetate	416-984-3000
Chemical Synonyms	N/A	NFPA
Formula	CH ₃ COOK	HAZARD RATING
CAS No.	127-08-2	LEAST 0 SLIGHT 1 MODERATE 2 HIGH 3 EXTREME 4

SECTION II DANGEROUS INGREDIENTS

Name	%	TLV Units
Potassium acetate	100%	N/A
CAUTION!		

SECTION III PHYSICAL DATA

Melting Point (°C)	292°C	Specific Gravity (H ₂ O = 1)	1.57 - 1.8 @ 20°C.
Boiling Point (°C)	N/A	Percent Volatile by Volume (%)	N/A
Vapor Pressure (mm Hg)	N/A	Evaporation Rate (= 1)	N/A
Vapor Density (Air=1)	3.4		
Solubility in Water	72.5% @ 20°C		
Appearance & Odor	White crystals; no odor. Hygroscopic.		

SECTION IV FIRE AND EXPLOSION HAZARD DATA

Flash point	Not flammable.	Flammable Limits in Air % by Volume	N/A	Lower	Upper
Firefighting Procedures	Use dry chemical, CO ₂ , alcohol foam, or water spray. In fire conditions, fire-fighters should wear an appropriate mask or a self-containing breathing apparatus.				

Flammability and Explosion Hazards

Fire or excessive heat may produce hazardous decomposition products to be produced as dust or fume.

TDG Not a TDG controlled material.

The information contained herein is furnished without warranty of any kind. Employers should use this information only as a supplement to other information gathered by them and must make independent determinations of suitability and completeness of information from all sources to assure proper use of these materials and the safety and health of employees. For laboratory use only. Not for drug, food or household use. Keep out of reach of children. Printed on recycled paper.

SECTION V	REACTIVITY DATA			
Chemical Stability	Yes	X	ILNo. under what conditions?	
Incompatible with Other products	Yes	X	Strong oxidizers.	

Hazardous Decomposition Products	Carbon oxides.
Reactive under what conditions	Not applicable.

SECTION VI TOXICOLOGICAL PROPERTIES

Route of Entry	Inhalation. Ingestion.
TLV	N/A
Toxicity for animals	Oral-rat: LD50: 3250 mg/Kg.
Chronic effects on humans	There are no known effects from chronic exposure to this product. Target organs: None known.
Acute effects on humans	May be harmful if swallowed. Contact may cause irritation to the skin and eyes.

SECTION VII PREVENTIVE MEASURES

Waste Disposal	Discharge, treatment, or disposal may be subject to local laws. Consult your local or regional authorities.
Storage	Keep container in a cool, well ventilated place. Keep away from heat. Keep away from incompatible materials.
Precautions	Avoid contact with skin and eyes. Do not breathe dust. Use with adequate ventilation. Do not ingest. If ingested, seek immediate medical attention.
Spill or leak	Use appropriate tools to put the spilled solid in a convenient waste disposal container. Wash spill area with soap and water.
Protective Clothing	Gloves, safety glasses, lab coat, dust respirator.

SECTION VIII FIRST AID MEASURES

Specific first aid measures

Ingestion: Call physician or Poison Control Center immediately. Induce vomiting only if advised by the appropriate medical personnel. Eye contact: Check for and remove any contact lenses. Immediately flush eyes with running water for at least 15 minutes, keeping eyelids open. Seek medical attention. Skin contact: Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Inhalation: Move victim to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Allow victim to rest in a well ventilated area. Seek immediate medical attention.

SECTION IX PREPARATION OF THE MSDS

Rev. No.	2	Date	November 14, 2002	Approved	Michael Raszeja
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MSDS Number: **T7112** * * * * * Effective Date: **01/31/03** * * * * * Supersedes: **11/02/01**

MSDS**Material Safety Data Sheet**

From: Mallinckrodt Baker, Inc.
222 Red School Lane
Phillipsburg, NJ 08865



24 Hour Emergency Telephone: 908-859-2151
CHEMTREC: 1-800-424-9300

National Response in Canada
CANUTEC: 613-496-6666

Outside U.S. and Canada
Chemtrec: 703-527-3887

NOTE: CHEMTREC, CANUTEC and National Response Center emergency numbers to be used only in the event of chemical emergencies involving a spill, leak, fire, exposure or accident involving chemicals.

All non-emergency questions should be directed to Customer Service (1-800-582-2537) for assistance.

TRIS HYDROCHLORIDE

1. Product Identification

Synonyms: 2-Amino-2-(hydroxymethyl)-1,3-propanediol, hydrochloride; Tris HCl; Tris (hydroxymethyl) aminomethane Hydrochloride

CAS No.: 1185-53-1

Molecular Weight: 157.59

Chemical Formula: C₄H₁₁NO₃ClH

Product Codes:

J.T. Baker: 1501, 4103, 4106, 4108

Mallinckrodt: H590

2. Composition/Information on Ingredients

Ingredient	CAS No	Percent	Hazardous
Tris Hydrochloride	1185-53-1	90 - 100%	Yes

3. Hazards Identification

Emergency Overview

WARNING! HARMFUL IF SWALLOWED. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 2 - Moderate

Flammability Rating: 1 - Slight

Reactivity Rating: 1 - Slight

Contact Rating: 2 - Moderate

Lab Protective Equip: GOGGLES; LAB COAT; VENT HOOD; PROPER GLOVES

Storage Color Code: Green (General Storage)

Potential Health Effects

Inhalation:

May cause irritation to the respiratory tract. Symptoms may include coughing and shortness of breath.

Ingestion:

Mild alkali. May cause irritation and reddening to the mucous membranes of the mouth, esophagus, and gastrointestinal tract. Large oral doses may cause weakness, collapse, and coma.

Skin Contact:

May cause irritation with redness and pain.

Eye Contact:

May cause irritation, redness, pain, and corneal damage.

Chronic Exposure:

Chronic dermatitis may follow skin contact.

Aggravation of Pre-existing Conditions:

No information found.

4. First Aid Measures

Inhalation:

Remove to fresh air. Get medical attention for any breathing difficulty.

Ingestion:

Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Skin Contact:

Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse. Get medical attention if irritation develops.

Eye Contact:

Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get medical attention if irritation persists.

5. Fire Fighting Measures

Fire:

As with most organic solids, fire is possible at elevated temperatures or by contact with an ignition source. Slight fire hazard when exposed to heat or flame.

Explosion:

Not considered to be an explosion hazard.

Fire Extinguishing Media:

Water spray, dry chemical, alcohol foam, or carbon dioxide.

Special Information:

In the event of a fire, wear full protective clothing and NIOSH-approved self-contained breathing apparatus with full facepiece operated in the pressure demand or other positive pressure mode.

6. Accidental Release Measures

Ventilate area of leak or spill. Wear appropriate personal protective equipment as specified in Section 8. Spills: Sweep up and containerize for reclamation or disposal. Vacuuming or wet sweeping may be used to avoid dust dispersal.

7. Handling and Storage

Keep in a tightly closed container, stored in a cool, dry, ventilated area.

Protect against physical damage and moisture. Separate from incompatibilities. Containers of this material may be hazardous when empty since they retain product residues (dust, solids); observe all warnings and precautions listed for the product.

8. Exposure Controls/Personal Protection

Airborne Exposure Limits:

None established.

Ventilation System:

A system of local and/or general exhaust is recommended to keep employee exposures as low as possible. Local exhaust ventilation is generally preferred because it can control the emissions of the contaminant at its source, preventing dispersion of it into the general work area. Please refer to the ACGIH document, *Industrial Ventilation, A Manual of Recommended Practices*, most recent edition, for details.

Personal Respirators (NIOSH Approved):

For conditions of use where exposure to dust or mist is apparent and engineering controls are not feasible, a particulate respirator (NIOSH type N95 or better filters) may be worn. If oil particles (e.g. lubricants, cutting fluids, glycerine, etc.) are present, use a NIOSH type R or P filter. For emergencies or instances where the exposure levels are not known, use a full-face positive-pressure, air-supplied respirator.

WARNING: Air-purifying respirators do not protect workers in oxygen-deficient atmospheres.

Skin Protection:

Wear protective gloves and clean body-covering clothing.

Eye Protection:

Use chemical safety goggles and/or full face shield where dusting or splashing of solutions is possible. Maintain eye wash fountain and quick-drench facilities in work area.

9. Physical and Chemical Properties

Appearance:

Transparent, colorless crystals.

Odor:

Odorless.

Solubility:

Soluble in water.

Density:

No information found.

pH:

No information found.

% Volatiles by volume @ 21C (70F):

0

Boiling Point:

Not applicable.

Melting Point:

150 - 151C (302 - 304F)

Vapor Density (Air=1):

No information found.

Vapor Pressure (mm Hg):

No information found.

Evaporation Rate (BuAc=1):

No information found.

10. Stability and Reactivity

Stability:

Stable under ordinary conditions of use and storage.

Hazardous Decomposition Products:

Burning may produce carbon monoxide, carbon dioxide, nitrogen oxides.

Hazardous Polymerization:

Will not occur.

Incompatibilities:

Copper, brass, aluminum, and oxidizing agents.

Conditions to Avoid:

Heat, flames, ignition sources and incompatibles.

11. Toxicological Information

No LD50/LC50 information found relating to normal routes of occupational exposure.

-----\Cancer Lists\-----

Ingredient	---NTP Carcinogen---		IARC Category
	Known	Anticipated	
Tris Hydrochloride (1185-53-1)	No	No	None

12. Ecological Information

Environmental Fate:

No information found.

Environmental Toxicity:

No information found.

13. Disposal Considerations

Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

14. Transport Information

Not regulated.

15. Regulatory Information

-----\Chemical Inventory Status - Part 1\-----				
Ingredient	TSCA	EC	Japan	Australia
Tris Hydrochloride (1185-53-1)	Yes	Yes	No	Yes

-----\Chemical Inventory Status - Part 2\-----				
Ingredient	Korea	DSL	NDSL	Phil.
Tris Hydrochloride (1185-53-1)	No	Yes	No	Yes

-----\Federal, State & International Regulations - Part 1\-----				
Ingredient	-SARA 302-	TPQ	List	-SARA 313-
	RQ			Chemical Catg.
Tris Hydrochloride (1185-53-1)	No	No	No	No

-----\Federal, State & International Regulations - Part 2\-----			
Ingredient	CERCLA	-RCRA-	-TSCA-
		261.33	8(d)
Tris Hydrochloride (1185-53-1)	No	No	No

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Solid)

Australian Hazchem Code: None allocated.

Poison Schedule: None allocated.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. Other Information

NFPA Ratings: Health: **1** Flammability: **1** Reactivity: **0**

Label Hazard Warning:

WARNING! HARMFUL IF SWALLOWED. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT.

Label Precautions:

Avoid contact with eyes, skin and clothing.

Avoid breathing dust.

Keep container closed.

Use with adequate ventilation.

Wash thoroughly after handling.

Label First Aid:

If swallowed, induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention. If inhaled, remove to fresh air. Get medical attention for any breathing difficulty. In case of contact, immediately flush eyes or skin with plenty of water for at least 15 minutes. Get medical attention if irritation develops or persists.

Product Use:

Laboratory Reagent.

Revision Information:

MSDS Section(s) changed since last revision of document include: 3, 7.

Disclaimer:

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Prepared by: Environmental Health & Safety
Phone Number: (314) 654-1600 (U.S.A.)